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|--|-------------|----------------------|---------------------------------|-----------------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
| 10/743,841   | 12/22/2003  | Anthony Viole        | FORFLOW.008DV1                  | 9080                        |
| 20995 7590 05/02/2008<br>KNOBBE MARTENS OLSON & BEAR LLP<br>2040 MAIN STREET<br>FOURTEENTH FLOOR<br>IRVINE, CA 92614 |             |                      | EXAMINER<br>BOCKELMAN, MARK     |                             |
|  |             |                      | ART UNIT<br>3766                | PAPER NUMBER                |
|  |             |                      | NOTIFICATION DATE<br>05/02/2008 | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/743,841 | <b>Applicant(s)</b><br>VIOLE ET AL. |  |
|                              | <b>Examiner</b><br>Mark W. Bockelman | <b>Art Unit</b><br>3766             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23, 28-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 13-23, 28-32 are rejected under 35 U.S.C. 102(b) as anticipated by  
or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mahurkar USPN  
5,374,245.

Murharkar teaches a triple lumen catheter that is used for dialysis system (pump). A connector portion 354 connects to the catheter and has indicators near where the catheter is joined. The examiner sees no reason why the entire catheter up to the connector, cannot be positioned entirely within the blood vessel (including the third lumen). The catheter may have a bend shape in it (j-tip) figure 50. The various lumens are in "communication" with all vessels of the body. Applicant's statements of intended use do not distinguish over Mahurkar. Applicant would do well to claim structural differences rather than intended use differences. While Mahurkar shows the triple lumen

embodiment with a single end, other embodiments show multiple external ends and one -23 reading the reference would conclude that such could be applied to the triple lumen embodiment. The multiple aperture on the lumens are also capable of providing a passive bypass lumen means, allowing blood into one aperture and out the other. If the tapered tips embodiment is selected and the third lumen has at least one aperture, the resulting catheter structure would look like the embodiment in figure 3 with the proximal aperture(s) capable of providing a bypass function. To the extent that the claims all read upon the embodiment shown in applicant's figure 6, the Murhurkar reference likewise reads upon the claims.

Claims 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mahurkar USPN 5,374,245. To have included radiopaque markers on the Mahurkar device so as to enable visualization of placement in the body would have been an obvious and notoriously well known modification.

Claims 28, 30-32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Valley et al USPN 5,766,151 (alone or in view of Cicciu et al USPN 4,897,077). Valley et al shows the placement of his catheter within the body in figure 2. Note femoral entrance access point 24 and the relative size of the catheter body 25. The examiner considers this configuration to allow blood to pass in the femoral artery past the access point due to the size differential. The examiner considers the relative size the means for and it is at least an equivalent to permit blood flow down stream. The distal tip of the catheter is shown as being position

in the aorta in figure 2. Different embodiments of the balloon catheter are shown beginning at figure 5a. Of particular note are the embodiments of figures 8a -8c. Note outer first elongate body 432/402 and second (inner) elongate body 446 which extends distally further than the first elongate body. Also note side aperture 422. Although access site 24 is not depicted up close one would realize that the relative size differences would allow flow past the access point in the femoral artery. Otherwise, as noted in Cicciu (claim 1. item (f)), it is important to maintain flow into the femoral artery so as to not block blood flow to the legs of the patient. One of ordinary skill in the art would recognize that this is an inherent feature to Valley, to size the catheters to not block blood flow, or at least an obvious one. To have used a tapered sheath as a means would also have been obvious.

Claims 28, 30 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cicciu et al. USPN 4,897,077. The examiner applies a similar interpretation Cicciu et al as that of Valley. The examiner interprets the first elongate member to be the IAB which inherently is positioned in the aorta, and the second elongate member to be the sheath 54. The sheath shape is tapered specifically to provide a passive means for permitting blood flow down stream of the insertion point. Note that tip 52 is positioned between the access point and the aorta.

### ***Response to Arguments***

Applicant's arguments filed 12-22-2003 have been fully considered but they are not persuasive. It is unclear as to what applicant is trying to cover in his specification.

For instance, applicant's figure 6 shows a distal port 20 and proximal ports 28. However it is unclear if the lumen that connects the port structures also extends proximally outside the patient. If this is the case, the Mahurkar reference as explained above by the examiner, anticipates or renders obvious, that figure. The intended use is given little patentable weight for the distal port and proximal apertures of Marhurkar are fully capable of providing a bypass function.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272 -4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Mark W Bockelman/  
Primary Examiner, Art Unit 3766  
April 28, 2008